MAY 0 3 2002

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K020375

1. **Submitter's Identification:**

Bailey Medical Engineering
2216 Sunset Drive
Los Osos, CA 93402

Contact: Barry Bailey

Phone: 805-528-5781
Fax: 805-528-1461

Date Summary Prepared: April 19, 2002

2. **Name of the Device:**

Nurture III Breast Pump

3. **Predicate Device Information:**

Gerber Precious Care and Medela 015

4. **Device Description:**

The Nurture III Breast Pump utilizes a diaphragm type vacuum pump operating on either 115 VAC/60 Hz or 220 VAC/50 Hz. The pump is actuated by a six position rotary switch, allowing four positions of varying motor speed and two standby positions. The pump motor is attached to a collection kit consisting of flanges, bottles, tubing, filter, gasket, adapter caps and bottle stands. All materials in proximity to the collected milk are made of food grade plastics.

The Nurture III uses a hydrophobic filter to isolate the collected milk from the pumping mechanism. Further isolation is achieved by the air flow always being away from the collected milk to the pump mechanism, then evacuated to the atmosphere. There is never air flow from the pump to the collected milk.

It is a semi-automatic breast pump, meaning that the release of vacuum pressure is achieved by the user lifting her finger from the vent hole located on top of the collection kit. The vacuum is then built up by covering the hole.

The pump may be used with a single collection kit for the pumping of one breast, or

SK 43

K020375
p. 2

may be used with a double collection kit for the simultaneous pumping of both breasts.

5. **Intended Use:**

The Nurture III Breast Pump is intended for use by lactating women to express their milk. The motor is safe for multiple users as long as each of those users has her own collection kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2002

Mr. Barry Bailey
Owner
Bailey Medical Engineering
2216 Sunset Drive
LOS OSOS CA 93402

Re: K020375
Trade/Device Name: Nurture III Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: March 29, 2002
Received: April 2, 2002

Dear Mr. Bailey:

This letter corrects our substantially equivalent letter of, May 3, 2002, removing it from prescription use status. The enclosed indication for use form reflects this change.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent for the indications for use stated in the enclosure to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-1180 Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638 2041 or at (301) 443 6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020375

Device Name: Nurture III Breast Pump

Indications For Use:

The Nurture III is intended for use by lactating women to express their milk. The motor is safe for multiple users as long as each of those users has her own collection kit.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

David A. Lagasse

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020375